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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,360	01/28/2005	Steven Streatfield Gill	3174.00010	5703
48924	7590	10/17/2006	EXAMINER	
KOHN & ASSOCIATES PLLC 30500 NORTHWESTERN HWY STE 410 FARMINGTON HILLS, MI 48334				POUS, NATALIE R
ART UNIT		PAPER NUMBER		
3731				

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/507,360	GILL, STEVEN STREATFIELD	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 August 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 3-15 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 3-9 is/are rejected.
- 7) Claim(s) 10-15 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Response to Arguments

Regarding the Drawings

Examiner acknowledges applicants statement of submission of corrected drawing sheets, however these are not present in the file. A copy of the corrected drawings is requested

Regarding Claim objections

Examiner acknowledges submission of amended claims to overcome claim objections. Prior objection is withdrawn.

Regarding 35 USC 112 rejections

Examiner acknowledges submission of amended claims to overcome 35 USC 112 rejections. Prior 35 USC 112 rejection is withdrawn.

Regarding Claim rejections

Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warner et al. (US 5643286) in view of Lobdill et al. (US 6413263)

Warner teaches a stereoguide comprising:

- first (16) and second (12) guide elements through which instruments are passed along an axis of insertion towards a target; characterized by a first clamp (38) attached to a (20) attached to the guide member (16) having a clamping position on the axis between the guide elements and the target, or on the opposite side (16, 12) of the guide elements for clamping instruments passing through the guide elements (fig. 1).
- wherein the or each clamp (38) is moveable away from its clamping position (it is noted that clamp (38) is a screw that untwists from portion (32) to unclamp)
- wherein the, or each clamp is swivelable away from its clamping position (it is noted that screw head (38) "swivels" when twisted).
- a second clamp (42) having a clamping position on the axis of insertion

Warner fails to teach wherein one of the clamps is carried by a leg extending from the second guide and clamps between the guide elements and the target. Lobdill teaches a stereotactic guide wherein clamp (18) is carried by a leg (32) extending from the guide and clamps between guide element (50) and target (48) in order to grip the instrument near the target. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Warner with a clamp carried by a leg extending from the second guide and clamps between guide elements and the target as taught by Lobdill in order to grip the instrument near the target.

Claims 7, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Warner and Lobdill in view of Durand (US 4504269). The combination of Warner and Lobdill teaches a stereoguide comprising all limitations of preceding dependent claim 1 as previously described, and further teaches the following method: inserting a wire (51) into a support tube (56); inserting the wire and support tube together along an axis of insertion toward the target via the guide elements of the stereoguide (Warner Column 5, proximate lines 55-68) removing the wire; and inserting the instrument to the target via the guide tube. Warner does not teach removing the support tube from the wire, leaving the wire in situ, inserting a guide tube around the wire towards the target, instead of using the cannula as a guide tube. However, examiner asserts that the method described in the application is a well known tube introduction method known as the "Seldinger Technique" described in the "Acta Radiologica" journal in 1953 and utilized in Durand. According to this well-known

method for introducing a tubular member into the body and as illustrated by Durand in figs. 9A-9J), a needle that inserted into the body, and a wire is inserted through the needle; the needle is then removed. The tube is then threaded into the body by being guided by the wire over which it is moving. The wire is then removed from the tube. This method is utilized in order to provide a less traumatic entry technique. It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the "Seldinger Technique" of insertion for the instrument holding cannula (50) with the combination of Warner and Lobdill as taught by Durand in order to provide a less traumatic entry technique for the cannula.

The combination of Warner, Lobdill and Durand further teaches wherein the insertion of the wire into the support tube results in the wire projecting from the end of the support tube (it is noted that in order to remove the insertion wire as required by Durand, the wire must be longer than the support tube).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Warner, Lobdill, and Durand and further as a matter of design choice.

The combination of Warner, Lobdill, and Durand teaches all of the limitations of preceding dependent claims 1, 7 and 8 as previously described, but fails to disclose wherein the wire projects from the support tube towards the target by about 25mm. Since the applicant has not disclosed that the wire projecting about 25mm from the support tube, solves any particular problem or provides any advantage over a system wherein the length of wire projecting past the support tube is not disclosed, it would

have been an obvious matter of design choice to provide the wire about 25mm past the support tube, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum range involves only routine skill in the art. *In re Aller*, 105 USPQ 184.

Allowable Subject Matter

Claims 10-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sven-Ivar Seldinger: Catheter replacement of the needle in percutaneous arteriography (a new technique). *Acta Radiologica*, Stockholm, 1953, 39: 368-376.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP
10/11/06


ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
10/15/06.